

### **REMARKS/ARGUMENTS**

This Amendment is submitted in response to the Office Action mailed January 16, 2007. At that time claims 1-14 and 16-19 were pending in the application. In the Office Action, the Examiner withdrew the previous rejection under 35 U.S.C. §112, ¶¶ 1 and 2. The Examiner also found claim 19 to be allowable. However, the Examiner rejected claims 1-14 and 16-19 under 35 U.S.C. §112 ¶ 2 as being indefinite. Additionally, the Examiner rejected claims 1-3, 5-9 and 13 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,710,502 issued to Wright, Jr. et al. (hereinafter "Wright, Jr.").

By this Amendment, claim 1 has been amended. Accordingly, claims 1-14 and 16-19 are presented for reconsideration by the Examiner.

### **REJECTION OF CLAIMS 1-14 and 16-19 UNDER 35 U.S.C. §112, ¶ 2**

In the Office Action, the Examiner rejected claims 1-14 and 16-19 under 35 U.S.C. §112 ¶ 2 as being indefinite. See Office Action, page 2. The Applicants respectfully traverse this rejection.

The Examiner rejected claims 1-14 and 16-19 because of the element "the compound has a Calcium Receptor Inhibitor Assay  $IC_{50}$  value of 30  $\mu M$  or lower." Applicants initially note that claim 19 does not depend from claim 1 and should not be included in the rejection under §112. By this Amendment, claim 1 was amended to recite "the compound has a Calcium Receptor Inhibitor Assay  $IC_{50}$  value of no greater than 30  $\mu M$ ." Exemplary support for this amendment can be found in the Present Application, page 66, lines 9-13. Therefore, no new matter has been added.

The Examiner has presented essentially three reasons why the element is allegedly indefinite. First, the Examiner argues that the original phrase "or lower" did not have definite metes and bounds because it technically includes an  $IC_{50}$  value of zero. See Office Action, page 2. Claim 1 was amended to recite an " $IC_{50}$  value of no greater than 30  $\mu M$ ," thus avoiding the Examiner's concern that the claim covers  $IC_{50}$  values of zero.

Second, the Examiner argues, “[i]t is not clear what assay conditions are needed to obtain such an IC<sub>50</sub> value. Thus, various factors could yield the same IC<sub>50</sub> value for different set[s] of compounds.” See Office Action, pages 2-3. As pointed out in the Amendment dated December 14, 2006, there is only one assay disclosed in the Present Application, and the conditions and procedure described is the assay are to be used to obtain the IC<sub>50</sub> value recited in the claims. The assay used to determine the IC<sub>50</sub> value for a claimed compound is clearly set forth on page 64, line 27 to page 66, line 13 and is titled “Calcium Receptor Inhibitor Assay.” One having skill in the art would be able to routinely perform the assay using the procedure described to determine the IC<sub>50</sub> value as claimed. Therefore, it is clear what assay conditions are needed to obtain the IC<sub>50</sub> value recited in claim 1, and the element meets the requirements of 35 U.S.C. §112, second paragraph.

Third, the Examiner argues that the element provides functional language and does not “define any structural attributes.” See Office Action, page 3. According to MPEP §2173.05(g), “There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper” (citing *In re Swinehart*, 439 F.2d 210 (CCPA 1971)). “A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step.” MPEP §2173.05(g). In the present case, the recitation of “the compound has a Calcium Receptor Inhibitor Assay IC<sub>50</sub> value of no greater than 30 μM” is used in association with the claimed structure to “define a particular capability...that is served by the recited [structure].”

Not only is this consonant with MPEP §2173.05(g), but it follows the direction provided in *In re Barr*, 444 F.2d 588, 595 (CCPA 1971), which states:

The real issue in any such case [of determining definiteness] is not whether the recital is ‘functional’ or ‘negative,’ but whether the recital sets definite boundaries on the patent protection sought – that is, whether

those skilled in the relevant art can determine what the claim does or does not read on.

Judged by this standard, it is clear that the element of the claimed compound having an "IC<sub>50</sub> value of no greater than 30  $\mu$ M" complies with the second paragraph of §112 because, as described above, the specification provides a clear assay providing details necessary for one skilled in the art to determine whether or not the claim reads on a given compound. Therefore, the element meets the requirements of 35 U.S.C. §112, second paragraph. Withdrawal of this rejection is respectfully requested.

**REJECTION OF CLAIMS 1-3, 5-9 and 13 UNDER 35 U.S.C. §102(b)**

Claims 1-3, 5-9 and 13 were rejected under 35 U.S.C. §102(b) as being anticipated by Wright, Jr. See Office Action, page 3. Applicants respectfully traverse this rejection.

It is well settled that a claim is anticipated under 35 U.S.C. § 102(b) only if "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP §2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." MPEP §2131, citing *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

As a result of this paper, claim 1 was amended so that n is 1, 2 or 3 and X<sup>2</sup> does not include lower alkyl. Exemplary support for this amendment can be found on page 39 of the Present Application, compound 64, demonstrating a compound wherein n is 3. Therefore, no new matter has been added. Claims 1-3, 5-9 and 13 do not read on the compounds disclosed in Wright, Jr., namely, 6-chloro-3-[4-(3-pyridyl)butyl]-4(3H)-quinazolinone and 6-bromo-3-[4-(3-pyridyl)butyl]-4(3H)-quinazolinone (Table 1) because n  $\neq$  4 and X<sup>2</sup> does not include lower alkyl. Because each and every claim element is not disclosed by Wright, Jr., the claims at issue are not anticipated. Withdrawal of this rejection is respectfully requested.

**CONCLUSION**

Applicants respectfully assert that claims 1-14 and 16-19 are patentably distinct from the cited reference, and request that a timely Notice of Allowance be issued in this case. If there are any remaining issues preventing allowance of the pending claims that may be clarified by telephone, the Examiner is requested to call the undersigned.

Respectfully submitted,

A handwritten signature in cursive script, reading "Kevin B. Laurence", written in black ink.

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